

These notes refer to the Human Fertilisation and Embryology Bill [HL] as introduced in the House of Lords on 8th November 2007 [HL Bill 6]

HUMAN FERTILISATION AND EMBRYOLOGY BILL [HL]

EXPLANATORY NOTES

INTRODUCTION

1. These explanatory notes relate to the Human Fertilisation and Embryology Bill [HL] as introduced in the House of Lords on 8th November 2007. They have been prepared by the Department of Health in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by Parliament.
2. The notes need to be read in conjunction with the Bill. They are not, and are not meant to be, a comprehensive description of the Bill. So where a clause or part of a clause does not seem to require any explanation or comment, none is given.

LIST OF ABBREVIATIONS USED IN THE EXPLANATORY NOTES

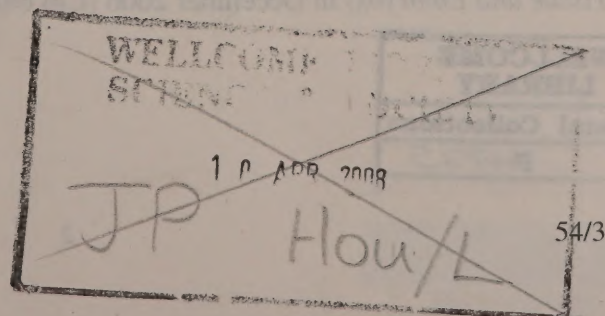
3. The following terms are used throughout the Explanatory Notes:

DI -	Donor Insemination
DNA -	Deoxyribose Nucleic Acid (genetic material)
ECHR	European Convention on Human Rights (2004/23/EC)
EU Directive	The European Union Tissue and Cells Directive
HFEA -	Human Fertilisation and Embryology Authority
IVF -	<i>In vitro</i> fertilisation
IA -	Impact Assessment
SI -	Statutory Instrument

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The 1990 Act -	The Human Fertilisation and Embryology Act 1990
The 2007 regulations -	The Human Fertilisation and Embryology (Quality and Safety) Regulations (SI 2007/1522) implementing the European Union Tissue and Cells Directive.

BACKGROUND

Review of the 1990 Act

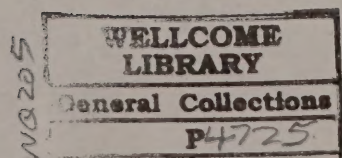
4. The provisions of the 1990 Act were enacted after consideration of the Report of the Committee of Inquiry into Human Fertilisation and Embryology, Chaired by Dame (now Baroness) Mary Warnock. This report was published in July 1984 and considered the social, ethical and legal implications of developments in the field of human reproduction, most notably the birth in 1978 of the first child conceived through *in vitro* fertilisation.

5. The 1990 Act regulates the creation, keeping and use of embryos outside the human body and the storage and use of gametes to create embryos. The 1990 Act prohibits certain activities from being carried out without a licence. Other activities including placing non-human embryos or gametes in a woman, are subject to an absolute prohibition.

6. Licences can be granted for the purpose of fertility treatment, for storage and for research. Following amendments made to the 1990 Act by the 2007 Regulations, a licence is also available under the 1990 Act in respect of non-medical fertility services. Non-medical fertility services are defined as any services that are provided, in the course of a business, for the purpose of assisting women to carry children, but which are not medical, surgical or obstetric services. In particular, they include a very small number of internet-based businesses that arrange for donated sperm to be delivered to women at home for self-insemination.

7. The 1990 Act imposes mandatory conditions on each type of licence and enables other conditions to be imposed. Activities under the 1990 Act are overseen by the HFEA, a statutory licensing authority.

8. In January 2004, the Government announced a review of the 1990 Act citing developments in reproductive medicine since the passage of the original legislation, and conducted a public consultation during the latter half of 2005. The Government followed this by publishing the White Paper: *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos)* in December 2006 (Cm 6989) containing policy proposals.



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9. Following publication of the White Paper a draft Bill was published in May 2007 for scrutiny by a Joint Committee of both Houses. Policy proposals from the White Paper as updated following pre-legislative scrutiny would be implemented by the Human Fertilisation and Embryology Bill [HL].

OVERVIEW

10. The purpose of the Bill is to amend the law relating to assisted reproduction treatment and embryo research. The Bill amends many of the provisions of the 1990 Act, but the main features of the existing model of regulation are retained.

11. The Bill is in three Parts. The first Part comprises amendments to the 1990 Act, the second Part makes provision about who is to be treated, after the coming into force of the Part, as the parent of a child who has been born as a result of assisted reproduction treatments, and the third Part makes miscellaneous and general provision.

Part 1

12. Part 1 (including Schedules 1 to 5) makes a range of amendments to the 1990 Act to take account of scientific developments, to reflect changes in societal attitudes and to update the HFEA's ability to regulate according to principles of better regulation.

13. To assist the reader of the Bill, the Department of Health has produced an illustrative consolidated text of the 1990 Act as amended. This will be available on the Department of Health website and in hard copy. This includes amendments made by the 2007 Regulations and shows the effect of the amendments made by the Bill. The text has no official status.

Part 2

14. Part 2 replaces existing provision under the 1990 Act to determine legal parenthood for future cases involving assisted reproduction. The Bill introduces a new concept of parenthood for a mother's female partner in certain circumstances, making equivalent provision to that for opposite sex couples.

15. The 1990 Act currently provides that where an unmarried couple are "treated together" in a licensed clinic using donated sperm, the male partner will be regarded as the father of any child born as a result. "Treated together" in this context is a somewhat loose concept. Part 2 makes provision that both the prospective mother and the man (or in the case of persons in a same-sex relationship, the woman) who is intended to be the second parent of the child must consent to such in writing.

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16. Part 2 also makes provision in relation to parenthood in respect of children born after a surrogacy arrangement, which is intended to put same sex couples and unmarried opposite sex couples in the same position as married couples.

Part 3

17. Part 3 of the Bill contains amendments to the Surrogacy Arrangements Act 1985, miscellaneous provisions and general provisions about order and regulation-making powers, powers to make consequential and transitional provisions, and commencement.

TERRITORIAL EXTENT

18. Part 2 of the Bill (and the free standing provisions in Part 3 of the Bill) extend to England and Wales, Scotland and Northern Ireland. The other provisions of the Bill amend existing legislation and have the same extent as the provisions being amended. This means, in particular, that the amendments of the 1990 Act in Part 1 of the Bill extend to England and Wales, Scotland and Northern Ireland.

19. The subject-matter of the 1990 Act and subject-matter of the Surrogacy Arrangements Act 1985 are reserved matters as respects Scotland and Northern Ireland. Part 2 of the Bill deals with a subject (the legal parenthood of children resulting from assisted reproduction) that is already dealt with by sections 27 to 30 of the 1990 Act. Part 2 therefore also relates to a reserved matter.

20. The HFEA will have powers to assist any other public authority in the UK as provided for in clause 9 of the Bill.

Wales

21. The Bill does not confer any functions on the National Assembly for Wales, and in general applies to Wales in the same way as it applies to England.

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Scotland

22. Because the Sewel Convention provides that Westminster will not normally legislate with regard to devolved matters in Scotland without the consent of the Scottish Parliament, if there are amendments relating to such matters which trigger the Convention, the consent of the Scottish Parliament will be sought for them.

Northern Ireland

23. The Bill does not contain any provisions that would invoke a legislative consent motion. Consequential amendments for Northern Ireland have been included.

COMMENTARY ON CLAUSES

PART 1: AMENDMENTS OF HUMAN FERTILISATION & EMBRYOLOGY ACT 1990

Clause 1: Meaning of “embryo” and “gamete”

24. This clause amends section 1 of the 1990 Act so as to ensure that the Act applies to all live human embryos regardless of the manner of their creation, and to all live human gametes (eggs and sperm).

25. An embryo will continue to be defined under the new section 1(1) in broad terms as a “live human embryo” but the definition no longer assumes that an embryo can only be created by fertilisation. This brings the term “embryo” up to date with technologies that have been developed since the time of enactment of the 1990 Act.

26. The definition of an “embryo” under the new section 1(1)(a) of the 1990 Act has been limited to exclude certain types of embryos created by combining together human and animal gametes, or human embryos altered using animal DNA or animal cells. Such entities are defined as “inter-species” embryos and are regulated under new section 4A of the 1990 Act inserted by clause 4.

27. The term “gametes” under section 1(4) of the 1990 Act has been amended to expressly encompass not only mature eggs and sperm, but also immature gametogenic cells such as primary oocytes, and spermatocytes.

28. A regulation-making power has been taken to expand the definitions of “embryo”, “eggs”, “sperm” or “gametes”, where this is considered by the Secretary of State to be necessary or desirable in light of developments in science or medicine (see new section 1(6)).

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Clause 2: Meaning of “nuclear DNA”

29. This clause inserts a new definition into section 2 of the 1990 Act to clarify that, the use of the term “nuclear DNA” includes DNA in both the nucleus and pronucleus of an embryo.

Clause 3: Prohibitions in connection with embryos

30. Clause 3 amends section 3 of the 1990 Act, which covers prohibitions connected with embryos. Section 3(2) prohibits the placing in any woman of any embryo other than a permitted embryo.

31. A permitted embryo is defined as an embryo which has been formed by the fertilisation of a permitted egg by a permitted sperm, whose nuclear or mitochondrial DNA has not been altered and that has not had cells added (apart from by division of the embryo’s own cells). Permitted eggs are defined as eggs produced or extracted from the ovaries of a woman and permitted sperm as sperm produced or extracted from the testes of a man. These eggs and sperm must also not have been subject to any alterations to their nuclear or mitochondrial DNA. This clause ensures embryos created by artificial gametes or genetically modified gametes could not be placed in a woman. Similarly, genetically modified embryos or embryos created by cloning cannot be placed in a woman. This prevents reproductive cloning and supersedes the Human Reproductive Cloning Act 2001.

32. A regulation-making power has been provided under new section 3ZA(5) of the 1990 Act to allow the meaning of permitted eggs and permitted embryos to be extended to include eggs or embryos that have been treated in such a way as specified in regulations to prevent the transmission of serious mitochondrial disease¹. In the future, it may be possible to create embryos using an affected woman’s egg, her partner’s sperm and healthy donated mitochondria. This regulation-making power will enable such embryos and eggs to be implanted in a woman if the technology became available and was proven safe. Further provision is made regarding mitochondrial donation in clause 26, which inserts new section 35A into the 1990 Act.

Clause 4: Prohibitions in connection with genetic material not of human origin

33. This clause inserts new section 4A into the 1990 Act to provide that certain types of embryo, which contain both human and animal DNA, are subject to

¹ Mitochondria are found outside the nucleus of the cell and contain a small amount of DNA. They are involved in energy production and are present in most cells in the body. If a woman’s egg is fertilised by sperm the mitochondria from her egg will become the mitochondria for every cell of the embryo formed. Therefore, if a woman has a genetic medical condition associated with her mitochondria, these will be inherited via her eggs.

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regulation under the 1990 Act. These are defined as “inter-species embryos” and include:

- Human-animal hybrid embryos: embryos created using a human egg and the sperm of an animal, or an animal egg and a human sperm or by combining a pro-nucleus of an animal with a human pro-nucleus (section 4A(5)(a));
- Cytoplasmic hybrids (Cybrids): embryos created by techniques used in cloning, using human cells and animal eggs. The embryos would be mostly human except for the presence of animal mitochondria (see the notes on clause 3 for more information on mitochondria) (section 4A(5)(b));
- Human transgenic embryos: embryos created by the introduction of animal DNA into one or more cells of the embryo (section 4A(5)(c));
- Human-animal chimeras: human embryos, altered by the addition of one or more cells from an animal (section 4A(5)(d)).

34. Regulation-making powers have been provided under new section 4A(5)(e) and 4A(7) to enable the Secretary of State to include within the definition of inter-species embryos other types of embryos or to amend the definitions in section 4A(5)(a) to (e) respectively.

35. Section 4A(2) prohibits mixing human gametes with the gametes of an animal and creating, keeping or using an inter-species embryo without a licence.

36. Section 4A(3) provides that any inter-species embryo created under licence cannot be kept after the earliest of either:

- the appearance of the primitive streak (an indicator for the start of a process by which the cells of the embryo begin to separate into three distinct cells types which will go on to form different types of tissue); or
- 14 days from the day on which the process of creating the inter-species embryo began.

This is consistent with the time limits for keeping human embryos *in vitro* for research purposes.

37. Further provisions about the licensing of activities involving inter-species embryos are made in clauses 11, 12, 13, 15 and paragraphs 5 and 6 of Schedule 2 to the Bill.

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Clauses 5: Membership of the Authority: disqualification and tenure

38. Clause 5 introduces Schedule 1 which contains amendments to Schedule 1 to the 1990 Act. These relate to the conditions for disqualification for appointment to the chair, deputy chair and membership of the HFEA. In particular those who have been the subject of bankruptcy orders or certain criminal convictions, cannot be appointed to the HFEA.

Clause 6: Additional general functions of the Authority

39. Clause 6 amends section 8 of the 1990 Act relating to general functions of the Authority. It adds to the list of the HFEA's general functions in (i) requiring the Authority to maintain a statement of general principles and (ii) requiring the HFEA to promote compliance with the requirements imposed by the 1990 Act and with the Code of Practice under section 25 of the 1990 Act.

40. New section 8(2) gives the Authority power to charge for advice given under section 8(1)(c). It is intended that the charge would recover all or part of the costs of providing the advice.

Clause 7: Duties in relation to carrying out its functions

41. This clause requires the HFEA to carry out its functions effectively, efficiently and economically and to have regard to the principles of best regulatory practice in doing so.

Clause 8: Power to contract out functions etc.

42. Clause 8 inserts new sections 8B and 8C into the 1990 Act which give the HFEA power to make arrangements with a government department, a public authority or the holder of a public office for the carrying out of any function of the Authority. However, the HFEA will retain responsibility for carrying out its functions. This new flexibility will, for example, permit the Authority to arrange with another public body for that body to conduct inspections on behalf of the HFEA.

43. Similarly, the HFEA will have power to contract-out certain of its functions to a non-public organisation. The functions that may be contracted out do not include licensing, the right of entry and power of search and seizure; or the power to make subordinate legislation. The Secretary of State can by order prevent any function of the HFEA from being contracted out. New section 8C(1)(a) also prevents the contracting out of any function which, by virtue of any enactment, may be exercised only by members of the Authority (8C(1)(c)).

44. Clause 8 also inserts new section 8D which provides the necessary authority for those exercising HFEA functions under an agency arrangement or contract, to

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receive and disclose information, such as that contained on the HFEA register, where this is necessary or expedient for the purpose of exercising the relevant function.

Clause 9: Power to assist other public authorities

45. Clause 9 introduces new section 8E into the 1990 Act which allows the HFEA to provide assistance to any other public authority in the UK. The HFEA may charge a fee for these services. It is intended that the fee would recover the costs of providing the assistance. This allows the HFEA to carry out functions on behalf of another organisation.

Clause 10: Power to delegate and establish committees

46. Clause 10 introduces new section 9A into the 1990 Act. *Subsection* (1) of 9A provides that the HFEA may delegate its functions to a committee or a member of the Authority, or to the Authority's staff. *Subsection* (2) provides that the HFEA may establish committees and sub-committees which may, in accordance with *subsection* (3) include people who are not members of the Authority. This provision replaces that in section 9 of the 1990 Act requiring licence committees to be comprised only of members of the Authority. These new provisions will enable the HFEA to delegate any function, apart from those which can only be exercised by members, to its staff or to a committee. These functions can include licence decisions and development of the Code of Practice.

Clause 11: Activities that may be licensed

47. This clause refers to Schedule 2 to the Bill which amends Schedule 2 to the 1990 Act. These amendments relate to licensable activities, specifically embryo testing and amending the purposes for which research licenses can be granted including the creation, keeping and use of inter-species embryos.

Licences for treatment

48. Paragraph 2 of Schedule 2 to the Bill amends paragraph 1 of Schedule 2 to the 1990 Act to enable treatment licences to be granted for the use of embryos for training purposes, but only where the HFEA is satisfied that such use is necessary. Paragraph 1 is also amended to ensure that only "permitted embryos" within the meaning of new section 3ZA can be placed in a woman. The Bill substitutes new provision for paragraph 1(4) of Schedule 2 so as to prevent a treatment licence authorising the alteration of the nuclear or mitochondrial DNA of a cell while it forms part of an embryo. This is subject to any regulations under new section 3ZA(5) as inserted by clause 3.

Embryo testing

49. The Bill adds paragraphs 1ZA to 1ZC to Schedule 2 to the 1990 Act which concern embryo testing, and practices designed to secure that a resulting child will be of one sex rather than the other.

50. Embryo testing involves invasive procedures such as embryo biopsy, involving removal of a cell or cells from the embryo for subsequent analysis. The effect of the new provisions is that testing of an embryo can only be authorised for the purposes in new paragraph 1ZA(1)(a) to (e). For example, *sub-paragraph* 1(a) could authorise testing to establish whether an embryo contained an abnormal number of chromosomes likely to result in miscarriage, sometimes referred to as preimplantation genetic screening. *Sub-paragraph* 1(b) could, for example, authorise testing to establish the presence or absence of a genetic disorder in a case where there was a particular risk of such an abnormality being present, sometimes referred to as preimplantation genetic diagnosis. A particular risk might be evidenced, for example, by a family history of the disease.

51. *Sub-paragraph* 1(c) refers to establishing the sex of an embryo where there is a particular risk that any resulting child will have or develop a gender-related serious physical or mental disability, serious illness or other serious medical condition. This provision enables sex selection not only for conditions which are clearly linked to sex chromosomes, for example Duchenne Muscular Dystrophy but also where there is a particular risk of gender-related conditions for example a strong family history of breast cancer where the mother has also been affected (and therefore is probably a carrier of the faulty gene), and wishes to avoid passing this condition on to a daughter.

52. Paragraph 1ZA(1)(b) is subject to the further provisions set out in *sub-paragraph* (2). *Sub-paragraph* (2) provides that in order for testing to be authorised under *sub-paragraph* (1)(b), the HFEA must be satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

53. A provision of clause 14 is closely related to the provisions on embryo testing discussed above. Clause 14 amends the 1990 Act to make it a condition of a treatment licence that, in the circumstances described, embryos that are known to have an abnormality as described are not to be preferred to embryos not known to have such an abnormality. The same restriction is also applied to the selection of persons as gamete or embryo donors. Similarly for sex selection, embryos of a particular sex that are at a particular risk, compared to embryos of that sex in general, of a gender related disability, illness or medical condition, should not be preferred to those that are not known to be at risk (see note on clause 14).

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Tissue typing

54. Paragraph 1ZA(1)(d) is concerned with “tissue typing” – establishing whether the embryo would result in a child whose tissue was compatible with that of an existing child (the sibling). Embryo testing for this purpose could be licensed where the sibling suffers from a serious medical condition that could be treated with matched tissue from the sibling including stem cells found in umbilical cord blood and bone marrow.

Testing in the event of uncertainty

55. Paragraph 1ZA(1)(e) is intended to ensure that embryos can be tested in order to resolve any uncertainty that has arisen as to the identity of the persons who provided the gametes used to create the embryo.

Sex selection

56. Currently as a matter of policy, the HFEA does not allow sex selection except for medical reasons. This position is maintained in the Bill. Paragraph 1ZB deals more generally with practices of sex selection for example sperm sorting, and precludes them from being authorised by a licence other than where there is a particular risk that a woman will give birth to a child who will have or will develop a gender-related serious physical or mental disability, serious illness or other serious medical condition. (see note in paragraph 51). Paragraph 1ZB does not prevent any embryo testing practices that may be permitted under paragraph 1ZA (see paragraph 51).

57. Paragraph 1ZC provides regulation-making powers to amend new paragraph 1ZA (embryo testing), and to make consequential amendments of the new paragraph 1ZB (sex selection). However, regulations may not authorise testing embryos to establish their sex or other practices of sex selection, except on grounds relating to the health of any resulting child.

58. Paragraph 4 of Schedule 2 to the Bill is intended to prevent sex selection in the context of the provision of non-medical fertility services. A licence cannot authorise the procurement or distribution of sperm to which any process has been applied which is designed to result in a child of a specific sex.

Licences for research

59. Under paragraph 3 of Schedule 2 to the 1990 Act, a research licence may authorise the creation, keeping and use of human embryos for the purposes of a

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project of research. Paragraph 6 of Schedule 2 to the Bill substitutes new paragraphs 3 and 3A for the existing provision.

Purposes for which embryo research may be undertaken

60. A research licence may not authorise any activity unless the HFEA considers it to be necessary or desirable for one of the specified research purposes.

61. The list of permitted research purposes was extended by the Human Fertilisation and Embryology (Research Purposes) Regulations, (SI 2001/188) (“the 2001 Regulations”) which allowed embryos to be created and used for research into stem cell therapies and the treatment of serious disease. New paragraph 3A brings together all the research purposes currently listed in the 1990 Act and the regulations made in 2001. It also makes three significant changes to the previous position on licensable research using embryos.

62. The list of purposes for which research may be licensed has been expanded in new paragraph 3A(2)(a) to include research which is undertaken to increase knowledge, not only about serious diseases, but also about other serious medical conditions. This includes conditions such as neural trauma or other tissue damage, which would not be considered to be diseases and therefore would not previously have been permitted.

63. New paragraph 3A(2)(b) allows for research into the development of treatments for other serious medical conditions, as well as for serious disease. Research may lead to an understanding of how to change stem cells into particular tissues, which may have the potential to regenerate or repair tissue damage caused by disease or trauma.

64. New paragraph 3A(1)(b) extends an existing provision, giving the HFEA power to not only issue licences where it is necessary or desirable for one of the principal purposes, but also where the research will increase knowledge about serious disease or other serious medical conditions, or develop treatments for them.

65. The 2001 Regulations have been superseded and are therefore revoked by Part 2 of Schedule 8 to the Bill.

Genetic modification of cells

66. Currently, paragraph 3(4) of Schedule 2 to the 1990 Act prohibits alteration of the genetic structure of the cell of an embryo, except in such circumstances as may be specified in regulations. No such regulations have in fact been made. This

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prohibition is not included in the re-enacted paragraph 3, therefore research involving the genetic modification of embryos may now be authorised under a research licence.

Inter-species embryos

67. Paragraph 3(2) of Schedule 2 to the 1990 Act, as inserted by paragraph 6 of Schedule 2 to the Bill, continues to allow the mixing of sperm with the egg of a hamster, or other animal specified in directions, for the purposes of research into the normality or fertility of sperm. Any resulting inter-species embryo must be destroyed as soon as the research is complete and no later than the two-cell stage.

68. New paragraph 3(3) enables licences to be issued to create, keep and use inter-species embryos defined under new section 4A(5)(a) to (d) as inserted by clause 4 for the purposes of a project of research specified in the licence.

69. Where regulations under section 4A(5)(e) provide for any other thing to be treated as an inter-species embryo, paragraph 3(5) provides a further regulation making power to allow such inter-species embryos to be created and kept and used for the purposes of a project of research.

70. New paragraph 3(6) provides that no research licence can be granted unless the proposed use of embryos or inter-species embryos is necessary for the purposes of the research.

71. New paragraphs 3(7), (9) and (10) of Schedule 2 to the 1990 Act deal with time limits and conditions applying to research licences.

Licences for storage (of inter-species embryos)

72. Under paragraph 2 of Schedule 2 to the 1990 Act, a storage licence may authorise the storage of gametes or embryos, or both. Paragraph 5 of Schedule 2 to the Bill inserts new *sub-paragraph* (1A) into paragraph 2 of Schedule 2 to the 1990 Act allowing the storage of inter-species embryos (regardless of whether the licence holder is already licensed to store embryos or gametes). Any such licence would be subject to the same conditions and time limits under paragraph 2(2) and (3) of Schedule 2 to the 1990 Act as licences to store embryos and gametes.

Clause 12: General conditions of licences

73. Section 12 sets out general conditions that apply to every licence granted under the 1990 Act. The 2007 regulations amended section 12 to except non-medical fertility services from the ambit of Schedule 3 to the 1990 Act. Neither the remit of the EU Directive or the powers under which it was implemented allowed for the

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consent provisions in Schedule 3 to the 1990 Act about the use and storage of gametes and embryos to be applied in the case of persons providing gametes for the purpose of the provision of non-medical fertility services. This clause amends section 12 of the 1990 Act to rectify that situation.

74. Clause 12 also amends section 12 to ensure that no money or other benefit can be given or received for the supply of inter-species embryos (unless authorised by directions) and that if inter-species embryos are supplied to a person to whom another licence applies they must be provided with any information that the HFEA may specify in conditions. These amendments ensure that any research licence granted in connection with an inter-species embryo will be subject to the same relevant licence conditions as for embryos or gametes.

Clause 13: Consent to use or storage of gametes, embryos and inter-species embryos etc

75. Clause 13 introduces Schedule 3 to the Bill which amends Schedule 3 to the 1990 Act, relating to consent to store or use embryos or gametes to create an embryo *in vitro*.

Formalities of consent

76. Schedule 3 to the 1990 Act states that consent for the storage and use of gametes and embryos is required in writing. This requirement for written consent is retained, but the Bill also provides that the consent must be signed.

Physical incapacity

77. People who have suffered an injury resulting in a condition such as quadriplegia or a similar condition may lack the physical ability to sign the consent form although they have the capacity to consent. New paragraph 1(2) of Schedule 3 to the 1990 Act will allow a physically incapacitated person, who is unable to write and therefore give consent in writing, to direct another to sign on their behalf, in the presence of a witness.

Purpose of consent

78. Under the 1990 Act, consent must specify the purposes for which any gamete or embryos are to be used. The Bill amends paragraph 2(1) of Schedule 3 so that, in addition to being able to consent to the use of embryos for treatment or research, a person may now also specify that an embryo can be used in the training of embryologists.

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Variation and withdrawal of consent

79. Paragraph 4 of Schedule 3 to the 1990 Act requires that a person withdrawing their consent to the storage and/or use of gametes or embryos gives notice of this to the establishment holding the gametes/embryos. New paragraph 1(1) of Schedule 3 will specify that this notice must be provided in writing and signed by the person withdrawing consent.

80. Paragraph 7 of Schedule 3 to the Bill inserts new paragraph 4A to Schedule 3 to the 1990 Act and introduces a “cooling off period” where one person in a couple seeking fertility treatment withdraws their consent to the storage of an embryo or, where donated gametes are used, where the gamete donor withdraws consent. This provision does not alter the existing requirement that the consent of both parties is required to store the embryos but it is intended to provide a year-long “cooling off” period during which the embryos will not be destroyed until all interested persons (see paragraph 4A(3)) consent. There is also to be a “cooling off” period where a single woman seeks fertility treatment and the gamete donor or donors withdraw consent.

81. This provision will allow embryos to remain lawfully stored while the parties, if they wish, attempt to reach a private resolution on the future of the embryos. If the interested persons do not agree to the embryos being removed from storage or simply do not respond to the notification, the embryos will remain in storage until the one year period expires after which they would be allowed to perish.

Non-medical fertility services

82. Paragraph 5 of Schedule 3 to the 1990 Act provides that a person’s gametes must not be used for the purpose of treatment services unless there is an effective consent. The Bill makes provision to also apply this condition where a person’s gametes are used for the purpose of non-medical fertility services.

Consent to use of human cells

83. Current provision under paragraphs 6 and 8 of Schedule 3 to the 1990 Act require the consent of any gamete donor before an embryo can be created *in vitro* using their gametes for one of the purposes listed in paragraph 2(1). Consent must also be obtained from a gamete donor to storage of their gametes, and any embryo created using their gametes.

84. New scientific procedures have enabled embryos to be created or altered using human cells. It is also possible to create embryos using other embryos or interspecies embryos.

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85. Paragraph 6 of Schedule 3 to the 1990 Act is amended by paragraph 9 of Schedule 3 to the Bill to require an effective consent from a person whose gametes or human cells are used to create an embryo *in vitro* for use in treatment services (not including implantation) or for a project of research.

86. Consent is also required from each “relevant person” in relation to an embryo for its use for any purpose (see paragraph 6(3)). In addition consent from each “relevant person” must be in place before an embryo is received by any person.

87. New sub-paragraph (3A) is inserted into paragraph 6 to provide that a “relevant person” includes

- each person whose gametes or human cells were used to bring about the creation of the embryo (embryo A);
- each person whose gametes or human cells were used to create an embryo *in vitro*, which was then used to create embryo A; and
- each person whose gametes or human cells were used to create an inter-species embryo *in vitro*, which was then used to create embryo A.

88. Paragraph 14 of Schedule 3 to the Bill inserts paragraph 16 into Schedule 3 to the Bill and provides that references to an embryo or inter-species embryo used to create an embryo include all predecessor embryos or inter-species embryos. This creates a chain of consent, so that a person must consent to their gametes or human cells being used to create an embryo and their consent is then required to the subsequent use of that embryo to create other embryos or inter-species embryos.

89. Paragraph 8 of Schedule 3 to the 1990 Act is amended by paragraph 11 of Schedule 3 to the Bill to require consent from each “relevant person” to storage of any embryo. Consent to storage of human cells continues to be regulated under the Human Tissue Act 2004.

90. Paragraph 2(4) of Schedule 3 to the 1990 Act is substituted to enable consent to relate to the use or storage of a particular embryo or to the use or storage of any embryo created using human cells or gametes (or using any embryo or inter-species embryo created using a person’s cells or gametes). Consent can be withdrawn or varied either in relation to a specific embryo or generally.

91. Paragraph 4 of Schedule 3 to the 1990 Act is also amended by paragraph 6 of Schedule 3 to the Bill to require notice to be given to the person keeping the human cells if the donor wishes to withdraw or vary their consent. This mirrors the existing provision for gametes and embryos. However if the person has consented to any embryo created from their cells or gametes being used to create subsequent embryos

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or inter-species embryos they will not be able to withdraw their consent once the initial embryo has been used for treatment services (not including implantation in a woman) or research.

92. Paragraph 7 of Schedule 3 to the 1990 Act is amended by paragraph 10 of Schedule 3 to the Bill to prohibit the use of an embryo taken from a woman to create an embryo *in vitro* or to create an inter-species embryo *in vitro*.

93. New paragraph 16 of Schedule 3 to the 1990 Act applies the consent provisions contained in Schedule 3 to the use of human cells to *alter* embryos or inter-species embryos, in the same way that they apply to human cells or gametes used to *create* embryos or inter-species embryos. This ensures consent is in place for example before human cells could be used to alter a human embryo to create a human chimera. New paragraph 16 of Schedule 3 also clarifies that references to human cells do not include cells of the female or male germ line or cells of an embryo.

94. Paragraphs 18 – 20 of Schedule 7 to the Bill amend the Human Tissue Act 2004 to ensure that consent must be obtained under the 1990 Act (as amended) for the use of human cells to create or alter an embryo or inter-species embryo.

Cases where consent not required for storage

95. Patients who undergo chemotherapy or radiotherapy can be left infertile. Prior to treatment, if time allows, fertility could be preserved by placing gametes in storage. However, in some cases, the patient might not have the capacity to give consent to storage. In the case of childhood cancer, a child may simply be too young to be considered competent to consent to storage of their gametes.

96. Similarly, people who suffer a serious physical injury, the treatment of which could again result in infertility, would also be able to preserve their fertility by this means. For example, a severe injury may have rendered an adult unable, perhaps because of a coma, to give consent or direct another person to do so on his or her behalf.

97. New paragraphs 9 and 10 of Schedule 3 to the 1990 Act will allow the storage of gametes, without written consent, providing a clinician certifies that the conditions set out in those paragraphs have been met. The gametes cannot be used for any purpose unless the gamete provider becomes competent and consents to such use.

Creation, use and storage of inter-species embryos

98. New paragraphs 13 - 15 are inserted into Schedule 3 to the 1990 Act by paragraph 13 of Schedule 3 to the Bill and introduce consent requirements for the creation, use and storage of inter-species embryos (as defined under new section 4A (5) of the 1990 Act, inserted by Clause 4 of the Bill). Inter-species embryos can be created using embryos, human cell, gametes and other inter-species embryos.

99. Paragraph 13 achieves equivalent provision to paragraph 6 of Schedule 3 to the 1990 Act (as amended by the Bill) and requires an effective consent before a person's gametes or human cells can be used to create an inter-species embryo *in vitro* for the purpose of a research project.

100. Consent is also required from each "relevant person" in relation to an inter-species embryo for its use in a research project (see paragraph 13(3)). In addition consent from each "relevant person" must be in place before an inter-species embryo is received by any person

101. New paragraph 14 of Schedule 3 to the 1990 Act achieves equivalent provision to paragraph 8 of Schedule 3 of the 1990 Act (as amended) and requires consent from each "relevant person" to storage of an inter-species embryo.

102. New paragraph 15 defines "relevant person" to include:

- each person whose gametes or human cells were used to bring about the creation of the inter-species embryo (inter-species embryo A);
- each person whose gametes or human cells were used to create an embryo *in vitro*, which was then used to create inter-species embryo A; and
- each person whose gametes or human cells were used to create an inter-species embryo *in vitro*, which was then used to create inter-species embryo A.

103. As for the creation of embryos, new paragraph 16 of Schedule 3 to the 1990 Act, as inserted by paragraph 14 of Schedule 3 to the Bill, provides that references to an embryo or inter-species embryo used to create an inter-species embryo include all predecessor embryos or inter-species embryos. This creates a chain of consent, so that a person must consent to their gametes or human cells being used to create an inter-species embryo and their consent is then required to the subsequent use of that inter-species embryo to create other embryos or interspecies embryos.

104. Paragraph 2 of Schedule 3 to the 1990 Act is amended to make equivalent provision to embryos for inter-species embryos. These amendments ensure that the

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consent to use of any inter-species embryo must relate to a research project and enables conditions to be attached to such use. In addition the consent must specify a maximum storage period and state what will happen to the inter-species embryo if the person who has consented dies or loses capacity. Conditions can also be attached to storage of the inter-species embryo.

105. Provision is made under the new paragraph 2(4) of Schedule 3 to the 1990 Act to allow a person to consent to the use or storage of a particular inter-species embryo or to the use and storage of any inter-species embryo created using a person's cells or gametes (or using an embryo or inter-species embryo created using their cells or gametes). Consent can be withdrawn or varied in relation to a specific inter-species embryo or generally.

106. Paragraph 4 of Schedule 3 to the 1990 Act is also amended to enable consent to be withdrawn or varied by notice to the person keeping the inter-species embryo. This ability to withdraw or vary consent in relation to an inter-species embryo is subject to the same limitation as for embryos set out at paragraph 91 above. This means once the initial inter-species embryo has been used for research purposes consent cannot be withdrawn or varied in relation to any further embryos or inter-species embryo created from it.

107. The amendments at paragraphs 92, 93 and 94 above also make provision in relation to inter-species embryos (as detailed).

Clause 14: Conditions of licence for treatment

108. This clause amends section 13 of the 1990 Act which relates to conditions of licences for treatment.

Embryo testing

109. Clause 14(4) contains a provision that relates to the provisions on embryo testing (see note on clause 11). New sections 13(8) to (11) amend the 1990 Act to make it a condition of a treatment licence that embryos that are known to have an abnormality (including a gender-related abnormality) are not to be preferred to embryos not known to have such an abnormality. The same restriction is also applied to the selection of persons as gamete or embryo donors. This would prevent similar situations to cases, outside the UK, where positive selection of deaf donors in order deliberately to result in a deaf child have been reported.

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Welfare of the Child

110. Currently, section 13(5) of the 1990 Act requires that:

“A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth.”

111. The HFEA is required by section 25(2) of the 1990 Act to provide guidance on this duty, and does so in its Code of Practice to licence holders. The relevant guidance² currently states:

“Where the child will have no legal father, the treatment centre should assess the prospective mother’s ability to meet the child’s/children’s needs and the ability of other persons within the family or social circle willing to share responsibility for those needs.”

112. Clause 14(2)(b) of the Bill removes the reference to a child’s need for a father from the licence condition to be imposed under section 13(5) of the 1990 Act. Clause 23 makes the same amendment to section 25(2) which concerns the guidance to be given about that condition. Section 13(5) will continue to require licence holders to consider the welfare of a child who may be born as a result of treatment (and any other child who might be affected) and will therefore continue to be a matter on which the HFEA must provide guidance.

113. Clause 14(6) makes transitional arrangements so that licences which are in force at the date of commencement of the Bill’s provisions will have effect as if they include the condition relating to consideration of welfare, as amended by clause 14(2)(b) of the Bill.

Welfare of the child where basic partner treatment services are provided

114. Basic partner treatment services are treatment services that are provided for a woman and a man together, without using donated gametes, gametes that have been stored, or embryos created outside the woman’s body. It will therefore comprise artificial insemination (intrauterine insemination, IUI) using sperm that has been processed but not donated or frozen. These services were brought within the HFEA’s remit by the 2007 Regulations.

115. Clause 14 (2)(a) applies the requirement to take account the welfare of the child where basic partner treatment services are provided in the same way that the requirement applies to other treatment services regulated under the 1990 Act.

² HFEA Code of Practice, 7th Edition, G.3.3.3

Requirement to offer counselling

116. Clause 14(3) and Schedule 4 to the Bill extend the existing requirements under the 1990 Act as to the provision of counselling by fertility clinics. Currently, under section 13 (6) of the 1990 Act, it is a requirement of all licences for treatment issued by the HFEA that a woman may not be provided with any treatment services involving donated gametes or embryos, or the use of an embryo which has been created *in vitro*, unless she and any man with whom she is being treated have been provided with relevant information and offered counselling. The new provision will extend this requirement to same sex couples. In addition, it will ensure that, before proceeding with embryo transfer or donor insemination, clinics are required to offer counselling to couples who have given notice that they consent to the intended mother's partner being treated as the parent of a child who is conceived using donor sperm. Where such notices have been given, but if one of the partners subsequently withdraws their consent, clinics will be required to notify the other partner of this.

117. The substituted section 13(6) is introduced to require that any woman and any partner of that woman who is receiving treatment with her, must be given a suitable opportunity to receive counselling *before* treatment is provided. The new section 13(6A) requires a suitable offer of counselling to be provided before two people being treated together consent to the parenthood of any child that may be born as a result of that treatment.

118. New section 13(6B) applies the new concepts of "agreed fatherhood conditions" and "agreed female parenthood conditions" to *subsection* (6A) as provided for under clauses 35 and 42 of the Bill.

119. The new section 13(6C) and (6D) provide that where either partner withdraws consent to agreed fatherhood or parenthood the person responsible for the clinic must notify the other partner. This includes where the woman being treated withdraws her consent for the other partner to be the parent of any resulting child. Where the partner of the woman receiving treatment withdraws their consent, the person responsible shall not place any embryo, sperm or eggs in the woman until she has been notified of it.

120. Schedule 4 to the Bill inserts a new Schedule 3ZA into the 1990 Act. Part 1 specifies treatment involving the use of donated gametes or embryos and the use of embryos created *in vitro* as the kinds of treatment in relation to which clinics must offer counselling in accordance with licence conditions imposed under section 13(6). Part 2 defines the events after which counselling must be offered in accordance with licence conditions imposed under section 13(6A) – that is, the giving of notices of consent to parenthood. The concept of two people (who are unmarried and are not

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civil partners) signing a parenthood agreement where donated embryos or gametes are used will provide a more formal arrangement to replace the current provision that refers to couples being “treated together”.

Clause 15: Conditions of storage licences

121. Clause 15 amends section 14 of the 1990 Act. Section 14, as amended, continues to provide for various conditions to apply to storage licences. Clause 15 amends the statutory conditions attached to storage licences and amends the maximum statutory storage limit for embryos to bring it into line with the ten-year limit applicable to the storage of gametes.

122. Currently, there is a five-year storage period. After this has expired, the Human Fertilisation and Embryology (Statutory Storage Periods for Embryos) Regulations 1996 (SI 1996/375) allow embryos to be kept in storage, for an additional five years, only if the couple are still considered to be infertile and the embryos are kept solely for their own treatment. Removing both the five year break point and the restriction on storage for personal use will allow couples to opt for a full ten year storage period at the outset and give them the opportunity, if they no longer wish to use the embryos themselves, to donate them for the treatment of others or for research. Couples will be able to take up this option at any point during the ten year period.

123. Section 14 is also amended to apply a ten year statutory storage period to inter-species embryos.

Clause 16: Grant of licences

124. This clause amends section 16 of the 1990 Act. It removes from section 16 of the 1990 Act the requirement for a licence application to be in a particular form and for an initial and an additional fee to be paid. Fees will be set in accordance with a scheme made by the HFEA under new section 35B of the 1990 Act set out at clause 27.

Clause 17: The person responsible

125. Clause 17 repeals the definition of “nominal licensee” from the 1990 Act. The term “nominal licensee” is no longer included because it does not adequately reflect the responsibilities of a licence holder.

Clause 18: Revocation and variation of licences

126. Clause 18 provides that the HFEA may revoke any licence or may vary a licence either on application by the licence holder, or the person responsible, or of its own volition. The power to vary a licence does not include the power to vary the mandatory conditions imposed by section 12 and 15 of the 1990 Act on every licence.

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Clause 19: Procedure for refusal, variation or revocation of licence

127. Clause 19 makes a number of small amendments to the procedures in the 1990 Act for notifying licensing decisions to interested parties. The HFEA will provide the applicant with notice of its proposed decision and reasons for the decision. Once a person has been given notice they will then have the right to make representations about the proposed decision. . If the HFEA proceeds with the decision, then section 20, (introducing by clause 21 of the Bill), provides that the applicant may apply for a reconsideration.

Clause 20: Power to suspend licence

128. This clause introduces new section 19C substituting section 22 of the 1990 Act concerning the Authority's powers to suspend a licence. Any period of suspension is restricted to a maximum of 3 months although this may be renewed. Appeals against a decision to suspend may be made to an appeals committee constituted under regulations made by the Secretary of State in the same way as other licensing decisions (see new section 20A of the 1990 Act).

Clause 21: Reconsideration and appeals

129. Clause 21 substitutes sections 20 and 21 of, and introduces new section 20A and 20B in, the 1990 Act.

130. Substituted section 20 sets out the rights of appeal against licensing decisions of the HFEA.

131. New section 20A provides that the HFEA must maintain one or more appeals committees. The constitution of appeals committees will be set out in regulations made by the Secretary of State. The regulations may also provide for advisors to be appointed to appeals committees so that the committees can receive specialist scientific, legal and other advice.

132. New section 20B provides that reconsideration of licensing decisions and suspension notices will be by way of a fresh decision. It provides for regulations to make provision about the procedure to be followed. Those regulations may in particular include provisions concerning the right of the appellant and the Authority to appear before the committee, for the committee to consider written representations, requirements concerning evidence and the production of documents; and requirements concerning decisions of the committee.

133. New section 21 provides that a further appeal may be made by to the High Court by a person aggrieved by the appeals committee's decision, but only on a point of law.

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Clause 22: Directions

134. Section 24 of the 1990 Act provides for directions to be given in respect of various matters. Clause 22 makes several amendments to this section, some of which concern the directions which may be given in respect of inter-species embryos and others which make updated provision concerning what is to happen when a licence is varied or ceases to have effect.

Clause 24: Register of information

135. Section 31 of the 1990 Act requires the HFEA to keep a register of information obtained by it which relates to the provision of treatment services, or the keeping or use of any gametes or an embryo taken from a woman, or the procurement or distribution of sperm for certain purposes. It also requires the HFEA to keep a register of information obtained by it about people born as a result of treatment services.

136. Section 31 makes provision for people conceived as a result of donated gametes since the 1990 Act came into effect to require the HFEA to provide them with certain information.

137. Donor-conceived people are able to find out whether they would be related, but for the provisions of the Act which determine parenthood in relation to people born as a result of certain treatment services (sections 27 to 29 of the Act), to the person they intend to marry and at age 18 they are able to find out whether the register shows that they were, or may have been, conceived using donor gametes. If so, they are able to obtain such information which is held on the register as is specified in regulations made under section 31(4).

138. The Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 (SI 2004/1511) specify the information which the HFEA must provide if a request is made by a donor-conceived person. Where information was provided by a donor before 1 April 2005, certain specified non-identifying information must be provided to the donor-conceived person. Where identifying information was provided by a donor after 31 March 2005 then certain identifying and non-identifying information must be provided. Those who ask for information from the register must be given an opportunity to receive counselling.

139. Donors who made their donation before 31 March 2005 but after the 1990 Act came into force, can opt to re-register as identifiable, and identifying information could also be released about them if a request was made by a person conceived as a result of their donation.

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140. Clause 24 of the Bill replaces section 31 with new sections 31 to 31ZG. New section 31 re-enacts the parts of the amended section 31 which deal with the register so that the HFEA must continue to keep a register of the information referred to above and must also record such information which it obtains after the Bill comes into effect.

141. New section 31ZA re-enacts the existing provisions of section 31 of the 1990 Act which enable a donor-conceived person (“the applicant”) to obtain information about their donor. However, the donor-conceived person will be able to request this information from age 16. Only non-identifying information can be disclosed whilst the donor-conceived person is under 18.

142. In new section 31ZA(2)(b) there is a further provision, that a donor-conceived person is entitled to information, at age 16, and on request, about the number, sex and year of birth of their donor-conceived half siblings who were conceived using gametes of the same donor but are not the donor’s legal children.

143. The HFEA has a discretion not to comply with a request for information about the genetic half-siblings if it is aware of special circumstances which increase the likelihood that the applicant would be able to identify the donor (in a case where the applicant does not have a right to obtain information about the donor’s identity) or any such genetic half-sibling.

144. New section 31ZB enables a donor-conceived person to find out whether they are related to someone they propose to marry, enter a civil partnership or intimate physical relationship with or with whom they are having an intimate physical relationship. The consent of the person they are in or intend to enter the relevant relationship with will need to be given to the HFEA. There is no age limit in relation to applications under this section by donor-conceived people who are intending to marry or enter a civil partnership. This is in line with the current provision in section 31. In order to make an application as a person who is in or is intending to enter into an intimate physical relationship, the donor conceived person must be aged 16 or over.

145. New section 31ZC gives the HFEA the power to inform a donor of the fact that a donor-conceived person has requested information about him. Donor conceived people will be able to request identifying information about their donor from 2023 onwards, in relation to donors who donated identifiably from April 2005. This could happen sooner if someone donated before April 2005 elected to re-register as identifiable, and a person conceived from his or her donation requested identifying information from the HFEA. In practice, the HFEA would try to forewarn the donor before identifying information is given to the donor-conceived applicant. This might

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not be possible in all cases, for example if the donor has moved and has not updated their address. The HFEA may not disclose identifying information about the donor-conceived person to the donor.

146. New section 31ZD enables donors (including past donors) to be provided with information on request about the number, sex and year of birth of children born as a result of their donations. They may ask the clinic where they donated or the HFEA (if the clinic has closed or the clinic is not able to, or fails to, provide the information). The information can be withheld from the donor if the HFEA is aware that circumstances exist which would mean that releasing the information would increase the likelihood that the donor would be able to identify a child born as a result of their donation.

147. New section 31ZE enables donor-conceived people to request and obtain identifying information about their genetic half-siblings who were conceived using gametes from the same donor, where neither is the donor's legal offspring. The half sibling whose information is being released must consent to the disclosure and both siblings must have had a suitable opportunity to receive counselling. There is also a proviso that the disclosure would not lead to the identification of a donor without the donor's consent unless regulations provide that his or her identity could be released to either of the donor-conceived people on request i.e. he/she is a non-anonymous donor.

148. New section 31ZF introduces a power for the HFEA to set up, or keep, a voluntary contact register of people who would like to receive information about any person to whom they are genetically related as a consequence of the provision to any person of assisted conception treatment services in the United Kingdom involving donors before the HFEA's register began on 1 August 1991. New section 31ZG enables the HFEA to fund, on such terms and conditions as the HFEA considers appropriate, another person or body to set up and keep a voluntary register.

149. If the HFEA keeps a register under new section 31ZF, it may charge a fee to people wishing to join it, arrange for DNA samples of people who join to be analysed, with their consent, and matched with those of others on the register, and make arrangements for information to be disclosed between people who are genetically related. It is intended that the fee charged would recover all or part of the costs of keeping the register. Such a voluntary contact register, UK DonorLink, has been run as a national pilot project since 2004 by After Adoption Yorkshire, a voluntary organisation.

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Clause 25: Restrictions on disclosure of information

150. This clause introduces new section 33A to the 1990 Act which will replace current section 33. New section 33A retains the prohibition on the disclosure of the information falling within section 31(2) of the 1990 Act.

151. Section 33 currently distinguishes between information which can be disclosed by the HFEA and information which can be disclosed by licence holders and persons to whom directions have been given. New section 33A places all persons who might hold information which is on the HFEA's register on a similar footing when it comes to lifting the prohibitions on disclosure. Information which has been obtained by any person as a member or an employee of the HFEA, a person to whom a licence applies, including those covered by third party agreements, those to whom directions from the HFEA have been given, and authorised people who are carrying out functions which have been contracted out to them by the HFEA (and their members of staff or employees), may not be disclosed except to the categories of person or in the circumstances specified in new section 33A(2).

152. Section 33A(2) lifts the prohibition on disclosure which section 33A(1) imposes. Exceptions to the prohibitions on disclosure are currently listed under section 33 of the 1990 Act, as amended by the Human Fertilisation and Embryology (Disclosure of Information) Act 1992 and the 2007 Regulations. Most of the current section 33 exceptions are being retained. Some are however being replaced, and additional exceptions have been included in new section 33A(2). For example, now section 33A(2) permits disclosure to other persons or bodies discharging a regulatory function and permits disclosure to authorised people who are performing functions contracted out to them by the HFEA, or under third party agreements, or with the consent of those to whom the information relates (in certain circumstances). Anyone considering whether it is lawful to disclose the relevant information will still need to satisfy themselves that the disclosure would not breach the Data Protection Act 1998 or any confidentiality rights. New section 33B provides a power to make further exceptions to 33A(1).

153. New section 33C enables the Secretary of State to make provision, in regulations, requiring or regulating the disclosure of information falling within section 31(2) for research purposes. Information can be disclosed for the purposes of medical research where the Secretary of State considers it necessary or expedient in the public interest or in the interests of improving patient care. Information can be disclosed for other research purposes if the Secretary of State considers it necessary or expedient in the public interest. Fees may be charged in accordance with regulations made by the Secretary of State for these purposes. The fees will be of a prescribed amount to be paid to the HFEA and it is intended that the fees charged would recover all or part of the costs of providing the information. Such research could include follow-up studies

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on the safety of IVF. The regulations may make provision for disclosure to be lawful despite any duty of confidentiality owed in relation to the information. It is expected that this power would only be used in such circumstances where it would not be possible to obtain consent to the disclosure.

154. Before making the regulations, the Secretary of State must consult, to the extent that he considers appropriate, such bodies who appear to represent the interest of those who are likely to be affected by the regulations. The regulations may make provision for a body to be established which will have the function of considering whether disclosure should be authorised, should the Secretary of State consider this to be the appropriate way forward.

Clause 26: Mitochondrial donation

155. Clause 3 of the Bill inserts new section 3ZA(5) into the 1990 Act to provide a regulation-making power to enable eggs and/or embryos with altered mitochondrial DNA to be classified as “permitted” eggs or embryos, and thus to be implanted in a woman (see note on clause 3 above).

156. The provisions of the 1990 Act assume that only one woman’s egg has been used to produce a child. New section 35A (inserted by clause 26) provides a further regulation-making power to amend specified sections of the 1990 Act if the power under new section 3ZA (5) is exercised. This enables provision to be made in cases where permitted embryos and/or eggs have been created using material from more than one woman. The relevant sections are set out in section 35A(2).

Clause 27: Fees

157. This clause sets out the circumstances where the HFEA may charge a fee under the 1990 Act. Fees are to be determined by the HFEA under a scheme determined by the Authority, subject to the approval of the Secretary of State and the Treasury. Different fees may be fixed for different circumstances and, in fixing the fee, the HFEA may have regard to the costs incurred in exercising its functions under the 1990 Act.

158. Clause 27 also provides a new power for the HFEA to charge fees to recoup the cost of meeting various statutory requests for information from donor-conceived people. In these cases, the amount of the fee can only reflect the cost of dealing with applications under the provision concerned.

Clause 28: Inspection, entry, search and seizure

159. This clause gives effect to Schedule 5 to this Bill which introduces Schedule 3B in to the 1990 Act. This Schedule replaces sections 39 and 40 concerning the power to enter, inspect and search premises and to seize items found on premises. It

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also deals with the obtaining and execution of warrants where an offence is suspected. It also provides that failure to comply with certain requirements under the Schedule or for obstructing any rights under it is an offence. Clause 28 also provides that it is not unlawful for a member or employee of the HFEA to be in possession of embryos, gametes or inter-species embryos in the course of their employment.

Clause 29: Offences under 1990 Act

160. Clause 29 relates to offences and penalties described in the 1990 Act, as extended by the Bill. It amends section 41 of the 1990 so as to extend the prohibitions introduced by the Bill including those relating to the creation or use of inter-species embryos without a licence; and sets out the circumstances where a defence can be raised under the 1990 Act. The requirement for consent of the Director of Public Prosecutions remains unchanged.

Clause 31: Power to make consequential provision

161. New sections 1 (6), 4A (5) (e) and 4A (7) of the 1990 Act provide a power to amend the definitions of “embryo” “gametes” and “inter-species embryo” under the 1990 Act by regulations. Clause 31 inserts new section 45A into the 1990 Act to enable consequential changes to other legislation as a result of amending any of these definitions. This includes modifying Acts of Parliament, Acts of the Scottish Parliament, Measures or Acts of the Welsh Assembly and Northern Ireland legislation and any secondary legislation made under them (with consultation with the devolved administrations where appropriate). The power under section 45A is exercisable by order.

Clause 32: Orders under the 1990 Act

162. Clause 32 inserts new section 45B into the 1990 Act. This states that the power to make an order under new section 45A and section 8C (1) (c) (see Clause 8) of the 1990 Act is exercisable by statutory instrument. The negative resolution procedure applies to section 8C (1) (c) but the affirmative procedure is applicable to new section 45A.

PART 2: PARENTHOOD IN CASES INVOLVING ASSISTED REPRODUCTION

Clause 33: Meaning of “mother”

163. Clause 33 re-enacts section 27 of the 1990 Act. It will remain the case that the woman who carries a child following assisted reproduction anywhere in the world is the child’s mother, unless the child is subsequently adopted or parenthood is transferred through a parental order.

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Clause 35: Woman married at time of treatment

164. There is no change to the existing position in relation to a child conceived as result of treatment with donor sperm by a married woman. Her husband will be treated as the child's father, unless it is shown that he did not consent to his wife's treatment. This provision (and others which operate to determine legal parenthood) is subject to the common law presumption that a child is the legitimate child of a married couple, as to which see the note on clause 38 below.

Clauses 36 and 37: Fatherhood conditions

165. The provisions of the 1990 Act which enable an unmarried man to be the father of a donor-conceived child if he is "treated together" with the mother in a licensed clinic are replaced by clauses 36 and 37. The new provisions require the couple to be treated in a UK licensed clinic, as before, to ensure there is clear evidence of the parents' intentions about fatherhood. However, for the man to be the father at the time the embryo or gametes have been placed in the woman or at the time she is artificially inseminated, the couple must each have given notice of consent to him being treated as the father. Neither of them must have given notice withdrawing that consent and the woman to be treated must not have given notice of consent to another man or woman being treated as the child's parent. The notices of consent do not necessarily have to be drawn up in the clinic, but they must be provided to the "person responsible" at the clinic. This is the person under whose supervision licensed activities are carried out. If, for example, a woman were to give notice of consent to several people being the father of a child, and there are corresponding notices given by the other persons, the latest set provided to the clinic would apply.

166. After the transfer of the gametes or embryo, neither the man nor the woman can withdraw their consent to the man being treated as the child's father unless the woman does not conceive and a new cycle of treatment has to begin. Changes to the conditions which must be included in all treatment licences, which are made by clause 14(3), will require that, if the man withdraws his consent at an earlier stage, the woman must be told before the treatment proceeds. She will therefore have the opportunity to decide whether she wishes to go ahead in these circumstances. If the woman withdraws her agreement to the man being the father, he must be told as soon as possible but he would not, through these provisions, be able to stop her going ahead if she wished to do so. Notices may not validly be given by two people who are within the prohibited degrees of relationship. This is defined in clause 58(2) to include parents and children, siblings and uncles/aunts and their nephew/nieces. Close relatives of this kind may not jointly be treated as a child's parents.

167. The Bill will maintain the situation that if an unmarried couple carry out self-insemination with donor sperm at home or elsewhere, not as part of licensed treatment, the male partner would not be the legal parent. He would have to take steps

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to acquire formal parental responsibility, for example by adopting the child. An unmarried man cannot become a parent where donor sperm is provided under a licence under paragraph 1A of Schedule 2 to the 1990 Act (non-medical fertility services) unless also used in treatment services.

Clause 38: Further provisions relating to sections 35 and 36

168. Clause 38(1) clarifies that where a person is treated as a child's father under the preceding clauses, no other person is to be treated as the father. A sperm donor, for example, would not have this status. Clauses 38(2) and (3) provides that clauses 35 and 36 do not affect the common law presumption that a child is the legitimate child of the parties to a marriage. If, for example, a woman marries between the conception of the donor-conceived child and its birth, it will be presumed that her new husband is the father of the child, even if the agreed fatherhood conditions were satisfied in relation to a different man at the time when the gametes or embryo were transferred. This presumption may, however, be rebutted by evidence (for example a DNA test) showing that the husband is not in fact the child's father. In that case, the provisions of clause 36 would apply and the man in respect of whom the agreed fatherhood conditions were satisfied would be the child's father. There is no parallel presumption at common law for people who enter a civil partnership. So the provisions which would otherwise apply to determine parenthood will not be affected by the mother entering into a civil partnership after the transfer of an embryo or gametes.

Clause 39: Use of sperm, or transfer of embryo, after death of man providing sperm

169. Clause 39 replaces provisions inserted into the 1990 Act by the Human Fertilisation and Embryology (Deceased Fathers) Act 2003. Clause 39 applies where a man's sperm, or an embryo created with his sperm, is used after his death. The man may be treated as the child's father for the purposes of birth registration only, if various conditions are met. The man must have consented, in writing, to the use of the sperm or embryo after his death and to being treated as the child's father for the purposes of birth registration. The woman must elect that he should be treated in this way within 42 days of the child's birth. This provision applies whether the embryo or gametes were transferred to the woman in the UK or elsewhere.

Clause 40: Embryo transferred after death of husband etc who did not provide sperm

170. Clause 40 makes similar provision to clause 39 for the case where donated sperm has been used. If the woman was married at the time of creation of an embryo using donor sperm and her husband dies before transfer of the embryo to her, she may elect that he should be treated as the child's father for the purposes of birth registration, subject to the consents described above. If the woman and man were not

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married at the time of creation of the embryo, there are additional requirements in that the agreed fatherhood conditions must have been met immediately before the man's death and the embryo must have been created in the course of licensed treatment services in the UK.

Clause 41: Persons not to be treated as father

171. This clause clarifies who is not the father of a child, for example a man who donates sperm for the treatment of another couple, or a man who has not consented to his sperm being used after his death.

Clause 42: Women in civil partnership at time of treatment

172. Clause 42 makes provision not found in the 1990 Act which brings the provision for female civil partners into line with that which applies to married couples. Where a female civil partner gives birth to a child conceived as a result of donor insemination (anywhere in the world), she is the mother of the child and her civil partner will automatically be the other parent, unless she did not consent to the mother's treatment. The terminology is different, but otherwise the legal provisions are the same as for married couples.

Clauses 43 and 44: Female parenthood conditions

173. Where one of the women has a child as a result of donor insemination in a UK licensed clinic and the couple have in place, at the time of the transfer of the sperm or embryo which results in conception, current notices of consent to the other woman being treated as a parent, then she will be a legal parent. This will reflect the provisions for an unmarried heterosexual couple who have a child. The same provisions about withdrawing consent and providing information to the other party will apply (see note on clauses 36 and 37). Again, notice cannot be given by two persons who are within the prohibited degree of relationship to each other.

Clause 45: Further provision relating to sections 42 and 43

174. Clause 45 provides that clauses 42 and 43 will not affect who is to be considered the parent of a child in various circumstances such as the presumption that a child is the legitimate child of a married couple or if the child had been adopted.

Clause 46: Embryo transferred after death of civil partner or intended female parent

175. This clause makes provision about registration of a deceased same sex partner as a child's parent in the register of births in certain circumstances. The provision for civil partners is comparable to that under clause 40 for married couples using donor sperm. The provision for other same sex couples is comparable to that for unmarried couples using donor sperm.

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Clause 47: Woman not to be other parent merely because of egg donation

176. Clause 47 makes clear that where a woman has not carried a child she will only be treated as a parent of the child if the provisions relating to parenthood of the mother's partner apply, or she has adopted the child. Being an egg donor will not make a woman the parent of a child carried by another woman, although parenthood could be conferred by other legal provisions. For example, if a woman donated an egg to her female partner, and the agreed female parenthood conditions were met in relation to her.

Clause 48: Effect of section 33 to 47

177. Clause 48 further explains the effect of provisions in new sections 33 to 47 of the 1990 Act. Where these new sections of the 1990 Act treat a person as the mother, father or parent of a child, or as not being the parent of the child, this status will apply for all legal purposes. However if a deceased man or woman is treated as the father or parent of a child under sections 39, 40 and 46 this will only apply for the purpose of those sections and will not apply for any other purpose.

178. The new parenthood provisions do not affect the succession to any dignity or title of honour in England, Wales and Northern Ireland or any property rights that relate to them. The provisions do not apply to any title, coat of arms, honour or dignity in Scotland or any property interest under the terms of a deed from devolving.

Clause 52: Late election by mother with consent of Registrar General

179. This clause allows for extension of the period during which a woman may elect for her deceased partner to be treated as her child's parent for the purposes of birth registration, with the consent of the relevant Registrar General.

Clause 53: Interpretation of references to father etc.

180. Clause 53 provides for references to a child's father in legislation and in other documents whenever passed or made to be read, in relevant cases, as references to a woman who is the child's parent by virtue of the Bill's provision for parenthood in clause 43. Although some legislation is expressly amended by Schedule 6 to take account of the possibility that a child may have two female parents, this provision will reduce the need for additional consequential amendments.

Clause 54: Parental orders

181. In clause 54 there are new provisions extending the categories of couples who can apply for a parental order (fast track adoption) where a child has been conceived using the gametes of at least one of the couple, and has been carried by a surrogate mother. Currently, only married couples can apply for a parental order. Under the new provisions, civil partners would also be able to apply, as would unmarried opposite-sex couples or same-sex couples not in a civil partnership. The other provisions

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relating to parental orders remain the same as the existing provisions of the 1990 Act. A single person remains unable to apply, but would be able to apply to adopt the child from the surrogate mother.

Clause 56: Amendments relating to parenthood in cases involving assisted reproduction

182. Clause 56 gives effect to Schedule 6, which contains amendments to legislation relating to parenthood in cases involving assisted reproduction.

AMENDMENTS IN PART 1 OF SCHEDULE 6

Births and Deaths Registration Act 1953

183. Paragraphs 1 and 2 of Schedule 6 amend sections 1 and 2 of the Births and Deaths Registration Act 1953 (particulars of births to be registered and information concerning birth to be given to registrar within 42 days) (“the 1953 Act”) so that the provisions extend to include a woman who is the parent of a child by virtue of clause 42 or 43 of the Bill. She is to be treated as the father for the purposes of the provisions.

184. Paragraphs 3 and 4 amend sections 9 and 10 of the 1953 Act (registration of father where parents are not married) so as to make provision for registration of the birth of a child where the second female parent of the child is not the civil partner of the mother (i.e. where clause 43 of the Bill applies).

185. Paragraph 5 substitutes section 10ZA of the 1953 Act (registration of father by virtue of certain provisions of the 1990 Act 1990) with a new section that applies both to fathers and to women who are to be treated as a parent by virtue of clause 46 of the Bill.

186. Paragraph 6 amends section 10A of the 1953 Act (re-registration where parents not married) so that it applies to re-registration where a woman is a parent of a child by virtue of clause 43 or 45(1) or (2) of the Bill (and who is not therefore the civil partner of the mother).

187. Paragraph 7 amends section 13 of the 1953 Act (registration of name or of alteration of name) so that a woman who is a parent of a child by virtue of clause 42 or 43 of the Bill is treated in the same way as a father of a child.

188. Paragraph 8 amends section 14 of the 1953 Act (re-registration of births of legitimated persons) to reflect consequential amendments to the Legitimacy Act 1976 as outlined below so that section 14 applies in the case of a legitimised person who is

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the child of a person who is the parent of the child by virtue of clause 43 of the Human Fertilisation and Embryology Bill [HL].

189. Paragraph 9 amends section 29A of the 1953 Act (alternative procedure for certain corrections of the register) so as to provide for correction of the register where a woman is wrongly registered as a parent of a person by virtue of clause 42, 43 or 46(1) or (2) of the Human Fertilisation and Embryology Bill [HL].

Registration of Births, Deaths and Marriages (Special Provisions) Act 1957

190. Paragraph 10 of Schedule 6 extends section 3A of the Registration of Births, Deaths and Marriages (Special Provisions) Act 1957 (alternative procedures for certain corrections to the register) (“the 1957 Act”) so as to provide for correction of the register where a woman is wrongly registered as a parent of a person by virtue of clause 40, 41 or 44(1) or (2) of the Human Fertilisation and Embryology Bill [HL].

191. Paragraph 11 amends section 5 of the 1957 Act (registration or re-registration of births of legitimised persons in the Service Departments Registers) to make provision in respect of the Service Departments Registers for a second female parent of a child by virtue of section 41 of the Bill to register or re-register a child following the subsequent formation of a civil partnership of the child’s parents.

Family Law Reform Act 1969

192. Paragraph 12 of Schedule 6 amends the definition of “excluded” in section 25 of the Family Law Reform Act 1969 (interpretation of Part 3) so that “excluded” also includes excluded by virtue of clauses 33 to 47 of the Human Fertilisation and Embryology Bill [HL]. The definition is relevant to section 20 of the 1969 Act which concerns the situation where the parentage of any person falls to be determined in civil proceedings. A report to the court must state whether any party to whom the report relates is or is not excluded by the results from being the father or mother of the person whose parentage is to be determined.

Congenital Disabilities (Civil Liability) Act 1976

193. Paragraph 13 of Schedule 6 amends section 1 of the Congenital Disabilities (Civil Liability) Act 1976 (civil liability to a child who is born disabled) (“the 1976 Act”) to extend the reference to “father” to include a woman who is the second female parent of a child by virtue of clause 42 or 43 of the Human Fertilisation and Embryology Bill [HL].

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194. Paragraph 14 amends section 4 of the 1976 Act (interpretation) so that references in section 1 of the Act to a parent include a person who would be a parent but for clauses 33 to 47 of the Human Fertilisation and Embryology Bill [HL].

Legitimacy Act 1976

195. Paragraphs 15 inserts new section 2A and paragraphs 16 to 18 amend sections 3, 9 and 10 of the Legitimacy Act 1976 to extend the existing provision to enable people who enter into a civil partnership and who have had children together previously by assisted conception, to legitimate those children as from the date of the civil partnership.

Magistrates Court Act 1980

196. Paragraph 20 substitutes a reference to section 30 of the 1990 Act (which is repealed by the Bill) with a reference to section 54 (parental orders) of the Human Fertilisation and Embryology Act 2008 in section 65(1) (na) of the Magistrates Court Act 1980 (meaning of family proceedings).

Supreme Court Act 1981

197. Paragraph 19 of Schedule 6 amends Schedule 1 to the Supreme Court Act 1981 to include parental orders under clause 52 of the Bill as matters to be assigned to the Family Division of the High Court.

British Nationality Act 1981

198. Paragraph 20 amends subsection (9A) of section 50 of the British Nationality Act 1981 (meaning of a child's father) to include, as "father" of a child for the purposes of that Act, the person who is to be treated as father of the child under section 28 of the Human Fertilisation and Embryology Act 1990 or clause 35 or 36 of the Bill (the husband of a woman who has a child by assisted conception, the male partner of an unmarried woman who has a child by assisted conception if the couple have a fatherhood agreement together), and the second female parent under clause 43, when the mother is in a civil partnership, or has a parenthood agreement in place.

Family Law Act 1986

199. Paragraph 21 inserts a reference to the proposed amendment inserting the new section 2A of the Legitimacy Act 1976 into section 56(5)(a) of the Family Law Act 1986 (declarations of the High Court or a county court regarding the parentage, legitimacy or legitimation of a person). This amendment extends the definition of a

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“legitimated person” to include someone who becomes legitimated under the new section 2A.

Family Law Reform Act 1987

200. Paragraph 22 amends section 1 of the Family Law Reform Act 1987 (general principles) (“the 1987 Act”) so that references in that Act and Acts passed subsequently to someone whose father and mother were married to each other at the time of birth are extended to include a person who was conceived through assisted conception at a time when their mother was in a civil partnership with another woman, or whose mother and second female parent were treated in a licensed clinic and had a parenthood agreement in force at the time the person’s mother was treated and who were civil partners either at the time of the child’s birth or at any time between treatment and the child’s birth. The amendments provide for civil partnerships which are void to be treated as valid for the purposes of this provision, where either or both of the parties reasonably believed that the civil partnership was valid.

201. Paragraph 23 amends section 18 of the 1987 Act (succession on intestacy) so that references to ‘father’ include a second female parent under clause 43 not in a civil partnership. Section 18 sets out the presumption that a person is not survived by an unmarried father who was not married to a child’s mother at the time of birth unless the contrary is shown, in cases of intestacy.

Children Act 1989

202. Paragraph 24 of Schedule 6 amends section 2 of the Children Act 1989 (“the 1989 Act”) to enable a second female parent to have parental responsibility for a child. A second female parent under clause 43 will have parental responsibility automatically where she and the mother of the child are in a civil partnership at the time of the fertility treatment, or where the mother and second female parent were treated in a licensed clinic and had a parenthood agreement in force at the time the child’s mother was treated and who were civil partners either at the time of the child’s birth or at any time between treatment and the child’s birth. The second female parent may also have parental responsibility if she acquires it in accordance with the provisions of the Act.

203. Paragraph 25 inserts a new section 4ZA into the 1989 Act (acquisition of parental responsibility by second female parent under clause 43). This new section provides for a second female parent with the mother at any time between the time of treatment and the birth of the child to acquire parental responsibility by registering as

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the child's parent in the register of births, by making a parental responsibility agreement with the child's mother, or by obtaining a court order.

204. Paragraph 26 inserts a new subsection (1A) in section 12 of the 1989 Act (residence orders and parental responsibility) which replicates for second female parents the provision in section 12(1) of the 1989 Act in relation to fathers. So that where a court makes a residence order in favour of a second female parent under clause 43, who does not already have parental responsibility, the court must also make a parental responsibility order under new section 4ZA.

205. Paragraph 27 amends section 91 of the 1989 Act (duration of orders) so that an order or agreement under new section 4ZA continues in force until the child is 18 unless it is brought to an earlier end.

206. Paragraphs 28 and 29 make minor amendments to section 104 (regulations and orders) and 105 (interpretation) to take account of new section 4ZA.

207. Paragraph 30 extends references in Schedule 1 to the 1989 Act (financial provisions for children) so that references to a child's father will also apply to a second female parent.

Human Fertilisation and Embryology Act 1990

208. Paragraph 31 amends section 32 of the 1990 Act 1990 ("the 1990 Act") to take account of children with a second female parent under clause 42 or 43 in cases where the Act enables the Human Fertilisation and Embryology Authority (HFEA) to comply with a request from the Registrar General to disclose information from the HFEA's register in respect of the parenthood of a child.

209. Paragraph 33 amends section 35 of the 1990 Act (disclosure of information: congenital disabilities) to update the reference to the provisions which determine the legal parenthood of a child if a court makes an order requiring the HFEA to disclose information from the HFEA's register for the purposes of proceedings under the Congenital Disabilities (Civil Liability) Act 1976.

Child Support Act 1991

210. Paragraph 34 of Schedule 6 amends section 26 of the Child Support Act 1991 (disputes about parentage) to include a reference to parenthood acquired via the new provisions for parental orders in clause 54 of the Bill; and also to the new parenthood provisions in Part 2 of the Bill.

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Family Law Act 1996

211. Paragraph 36 substitutes a reference to section 30 of the 1990 Act (which is repealed by the Bill) with a reference to section 54 (parental orders) of the Human Fertilisation and Embryology Act 2008 in section 63(2)(h) of the Family Law Act 1996 (definition of family proceedings).

Access to Justice Act 1999

212. Paragraph 37 substitutes a reference to section 30 of the 1990 Act (which is repealed by the Bill) with a reference to section 54 (parental orders) of the Human Fertilisation and Embryology Act 2008 in paragraph 2(3)(f) of Schedule 2 to the Access to Justice Act 1999 (community legal services; excluded services).

Adoption and Children Act 2002

213. Paragraph 38 substitutes section 51(4)(b) of the Adoption and Children Act 2002 (adoption by one person) to extend the circumstances in which a child can be adopted by one person, who is the child's natural parent, to include those where there is no other parent of the child under the Bill: by virtue of clause 35 (husband does not consent), 41 (sperm donor not to be treated as the father), 42 (female civil partner who does not consent) and 47 (woman not to be other parent merely because of egg donation).

Mental Capacity Act 2005

214. Paragraph 39 amends section 27 of the Mental Capacity Act 2005 (family relationships) and inserts subsection 1(1) to clarify that the provisions of the Mental Capacity Act 2005 do not enable a consent under the Human Fertilisation and Embryology Act 2008 to be made on behalf of another person.

AMENDMENTS IN PART 2 OF SCHEDULE 6

Children and Young Persons (Scotland) Act 1937

215. Paragraph 35 amends section 110(1) of the Children and Young Persons (Scotland) Act 1937 ('the 1937 Act'). This amendment provides that a second female parent is to be considered to have parental responsibilities for the purpose of offences under the 1937 Act, even where they have not registered for such responsibility under section 3(1)(d) of the Children (Scotland) Act 1995. This provides parity with the

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position for unmarried fathers who have not registered their parental rights and responsibilities under section 3(1)(b) of the Children (Scotland) Act 1995.

Registration of Births, Deaths and Marriages (Scotland) Act 1965

216. Paragraphs 36 of Schedule 6 amends section 14 of the Registration of Births, Deaths and Marriages (Scotland) Act 1965 (“the 1965 Act”) so that the provisions regarding the obligation to provide information relating to a birth extend to include a woman is the second parent of a child by virtue of clause 42 of the Bill.

217. Paragraph 37 substitutes existing section 18ZA of the 1965 Act (which governs circumstances in which a man is treated as the father if fertility treatment took place after his death) with a new provision which deals with both fathers and second female parents in that situation.

218. Paragraph 38 inserts new section 18B into the 1965 Act to apply equivalent provisions to those which deal with registration of a birth by an unmarried father to a person who is the second female parent by virtue of clause 41 of the Bill.

219. Paragraph 39 of Schedule 6 amends section 20 of the Registration of Births, Deaths and Marriages (Scotland) Act 1965 to accommodate within Scottish registration law the new category of second female parent created by section 41 of the Bill.

Family Law (Scotland) Act 1985

220. Paragraphs 40 and 41 of Schedule 6 amend sections 9(1)(c)(ii) and 27 (1) of the Family Law (Scotland) Act 1985 to extend references to ‘child of the family’ in relation to civil partners to include a child who is a child of both partners, by virtue of clauses 33 and 42 (where the partners were in a civil partnership at the time of treatment).

Children (Scotland) Act 1995

221. Paragraphs 42 to 44 of Schedule 6 amend sections 1(1), 2(1) and 3 of the Children (Scotland) Act 1995 (“the 1995 Act”) to deal with circumstances in which a second female parent will have legal parental responsibility for, and parental rights in relation to, a child.

222. Paragraph 45 and 46 of Schedule 6 amend section 4 and section 11 of the 1995 Act in order that a second female parent who is not in a civil partnership can acquire

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parental responsibility, by making a parental responsibility agreement with the child's mother, or by obtaining a court order.

223. Paragraph 47 of Schedule 6 amends section 12(4)(b) of the 1995 Act to extend the definition of "child of the family" in relation to civil partners. The extended definition includes a child who is a child of both partners, by virtue of clauses 33 and 42 (where the partners were in a civil partnership at the time of treatment).

Criminal Law (Consolidation) (Scotland) Act 1995

224. Paragraph 49 of Schedule 6 amends section 1(1) of the Criminal Law (Consolidation) (Scotland) Act 1995 so that the offence of incest applies as between mothers, fathers, second female parents (on the one hand) and their children (on the other) where that legal relationship is created as a result of this Bill.

Adoption and Children (Scotland) Act 2007

225. Paragraph 50 inserts a provision in section 30(7)(ca) of the Adoption and Children (Scotland) Act 2007 to extend the circumstances in which a child can be adopted by one person, who is the child's natural parent, to include those where there is no other parent of the child under the Bill: by virtue of clause 35 (husband does not consent), 41 (sperm donor not to be treated as the father), 42 (female civil partner who does not consent) and 47 (woman not to be other parent merely because of egg donation).

AMENDMENTS IN PART 3 OF SCHEDULE 6

Legitimacy Act (Northern Ireland) 1928

226. Paragraph 51 of Schedule 6 amends section 1 of the Legitimacy Act (Northern Ireland) 1928 to legitimise a person born to a woman as a result of assisted conception if the woman had a parenthood agreement in place with a second female parent at the time of the effective treatment in a licensed clinic, and she was not, at the time the child was born, in a civil partnership with that woman, but subsequently enters a civil partnership with her, provided that the second female parent is domiciled in Northern Ireland. The legitimisation takes effect from the date of the civil partnership.

227. Paragraph 52 amends section 8 of the Legitimacy Act (Northern Ireland) 1928 so that where a child is born as a result of assisted conception in a licensed clinic and a parenthood agreement is in place between the child's mother and a second female parent, and the couple are not civil partners at the time of the child's birth, but subsequently enter a civil partnership, and the second female parent who becomes a civil partner is domiciled outside Northern Ireland, and the law of her country of

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domicile legitimises that child, the child, if living shall in Northern Ireland, be legitimated from the date of the civil partnership.

Births and Deaths Registration (Northern Ireland) Order 1976

228. Paragraph 54 of Schedule 6 amends Article 10 of the Birth and Deaths Registration (Northern Ireland) Order 1976 to provide that the references to 'father' in Article 10(3) and (4) apply when a child who was conceived by assisted conception has a parent who is the civil partner of her mother, or has a second female parent because a parenthood agreement was in place at the time of the effective assisted conception treatment.

229. Paragraph 55 makes provisions for the various ways in which a birth may be registered, where a mother and second female parent under clause 43 have a child through assisted conception in a licensed clinic, are not civil partners but a parenthood agreement is in place. The registration may be made either by the couple together or separately, with appropriate formal declarations if the other party is not present, including as appropriate the provision of the parenthood agreement.

230. Paragraph 56 provides for the registration of a birth where a civil partner or intended female parent with a parenthood agreement in place dies before the fertility treatment which results in the birth of a child.

231. Paragraphs 57 and 58 provide for the re-registration of births where a child is born as a result of assisted conception to female civil partners, or to a female couple where a parenthood agreement is in place and there is no other person who is, in law, the father or parent of the child.

232. Paragraph 60 amends Article 37 of the 1976 Order by extending the definition of 'qualified applicant' to include a second female parent in cases where the second female parent has parental responsibility for the child whether or not she is the civil partner of the child's mother.

Child Support (Northern Ireland) Order 1991

233. Paragraph 61 of Schedule 6 amends Article 27 of the Child Support (Northern Ireland) Order 1991 to include a reference to parenthood acquired via the new provisions for parental orders in clause 52 of the Bill; and also to the parenthood provisions in Part 2 of the Bill.

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Children (Northern Ireland) Order 1995

234. Paragraph 63 amends Article 5 of the Children (Northern Ireland) Order 1995 to provide that a mother and a second female parent who are civil partners shall have parental responsibility for a child born through assisted conception. Where the second female parent of a child is not the civil partner of the child's mother that person shall have parental responsibility for the child if she has acquired it under Article 7 of the 1995 Order.

235. Paragraph 64 amends Article 7 of the Children (Northern Ireland) Order to provide for the means whereby a second female parent under clause 43 of a child conceived through assisted conception who does not become a civil partner of the child's mother, acquires parental responsibility; if she is registered as a parent of that child, or makes a parental responsibility agreement with the child's mother, or is given parental responsibility by a court.

236. Paragraph 65 amends Article 12 of the Children (Northern Ireland) Order 1995 and provides for a court which makes a residence order in favour of a second female parent of a child conceived through assisted conception to also give parental responsibility to that parent.

237. Paragraph 66 amends Article 155(3) of the Children (Northern Ireland) Order 1995 to include as legitimate someone conceived through assisted conception at a time when their mother was in a civil partnership, or who was born at a time when their mother was in a civil partnership, or whose mother and second female parent were treated in a licensed clinic and had a parenthood agreement in force at the time the person was conceived. The amendment takes account of civil partnerships which are void by the time the child is born.

238. Paragraph 68 amends Schedule 1 of the Children (Northern Ireland) Order 1995 so that references to the child's father are references to a child's second female parent.

239. Paragraph 69 amends Paragraph 1 of Schedule 6 of the Children (Northern Ireland) Order 1995, in relation to succession in cases of intestacy where parents are not married to each other, so that references to 'father' include second female parents.

PART 3: MISCELLANEOUS AND GENERAL

Clause 59: Surrogacy arrangements

240. Some women cannot carry a child for medical reasons. In a small number of cases, they ask another woman to be a surrogate mother and carry a child for them.

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Under the Surrogacy Arrangements Act 1985 (“the 1985 Act”) surrogacy arrangements are not enforceable in law.

241. To avoid the commercialisation of surrogacy, the 1985 Act prohibits organisations, or people other than intended parents or surrogate mothers themselves, from undertaking certain activities relating to surrogacy on a commercial basis.

242. Clause 59 allows bodies that operate on a not-for-profit basis to receive payment for providing some surrogacy services. It does so by exempting them from the prohibition in the current law.

243. The clause separates out into four categories the activities which are prohibited if done on a commercial basis. Not-for-profit bodies are permitted to receive payment for carrying out activity in two of those categories. The first is initiating negotiations with a view to the making of a surrogacy arrangement. A non-profit making body might charge, for example, for enabling interested parties to meet each other to discuss the possibility of a surrogacy arrangement between them. The second is compiling information about surrogacy. Not-for-profit organisations would, for example, be able to charge for establishing and keeping lists of people willing to be a surrogate mother, or intended parents wishing to have discussions with a potential surrogate mother.

244. It will remain the case that not-for-profit bodies will not be permitted to receive payment for offering to negotiate a surrogacy arrangement or for taking part in negotiations about a surrogacy arrangement. These activities are not unlawful if there is no charge, however.

245. The Bill also makes changes in relation to advertising by non-profit making bodies. Currently, under the 1985 Act, it is an offence to publish or distribute an advertisement that someone may be willing to enter into a surrogacy arrangement, or that anyone is looking for a surrogate mother, or that anyone is willing to facilitate or negotiate such an arrangement. The clause provides that this prohibition does not apply to an advertisement placed by, or on behalf of, a non-profit making body, provided that the advertisement only refers to activities which may legally be undertaken on a commercial basis. This would mean that a not for profit body could advertise that it held a list of people seeking surrogate mothers and a list of people willing to be involved in surrogacy, and that it could bring them together for discussion. But it would remain illegal for anyone to advertise that they wanted a surrogate mother or to be a surrogate mother.

These notes refer to the Human Fertilisation and Embryology Bill [HL] as introduced in the House of Lords on 8th November 2007 [HL Bill 6]

Clause 60: Exclusion of embryos from definition of organism in Part 6 of the EPA 1990

246. Clause 60 amends section 106 of the Environmental Protection Act 1990. Section 106 of the Environmental Protection Act defines “genetically modified organisms” but excludes human embryos as defined by the 1990 Act. Clause 60 amends this Act to also exclude inter-species embryos and human embryos as defined in the Bill (clauses 4(2) and 1(2) respectively).

FINANCIAL EFFECTS OF THE BILL & SUMMARY OF THE IMPACT ASSESSMENT

247. A separate full Impact Assessment (IA) has been produced to accompany the Bill, comparing the Government’s proposals with “do nothing” and de-regulatory options. This is available on the Department of Health website.

248. The analysis concludes that, in terms of benefits the Bill will update, and future-proof the law to deal with new situations and help maintain the UK’s position as a world leader in reproductive technologies.

249. The overall cost impact of the Bill is minimal as there are not increased costs as a consequence of introduction of the provisions in the Bill.

EFFECTS OF THE BILL ON PUBLIC SERVICE MANPOWER

250. The Government’s view is that the Bill would have no overall effect on public service manpower. As referred to in the section above, there will be financial implications arising in consequence of the proposed changes in relation to legal parenthood (notably in regard to births registration). However, the Government expects any impact on manpower to be negligible.

EUROPEAN CONVENTION ON HUMAN RIGHTS

251. In relation to licensing decisions to be made by the HFEA, the Bill’s provisions are compliant with Article 6 ECHR, which requires that, in the determination of civil rights and obligations, everyone is entitled to a fair and public hearing within a reasonable time by an independent tribunal established by law. The Bill provides for a two stage process of appeal, firstly to a committee of the HFEA itself, followed by a right of appeal to the High Court on a point of law.

252. The subject matter of the Bill also raises issues in relation to Articles 8, 12 and 14 ECHR, which respectively guarantee rights to protection of private and family life, the right to marry and found a family and freedom from discrimination in the

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enjoyment of rights under the Convention. Case law of the European Court of Human Rights in Strasbourg has established that, because there is no international consensus with regard to the regulation of IVF treatment or the use of embryos created by such treatment, and because the use of IVF treatment gives rise to sensitive moral and ethical issues against a background of fast moving medical and scientific developments, states are to be accorded a wide margin of appreciation in this area. The Government's view is that provision made by the Bill falls within this margin of appreciation. In some cases (for example, the extension of legal parenthood to same sex couples and availability of parental orders to unmarried and same sex couples) it is the Government's view that the provision made by the Bill will enhance the existing protection of rights under the Convention.

253. Case law of the European Court has also established that states have a broad margin of appreciation in determining the point at which life should begin to benefit from the protection guaranteed by Article 2 ECHR. The approach taken by the Bill, that embryos have no right to life which is protected by Article 2, is therefore in compliance with Convention obligations.

254. Section 19 of the Human Rights Act 1998 requires the Minister in charge of a Bill in either House of Parliament to make a statement about the compatibility of the provisions of the Bill with the Convention rights (as defined by section 1 of that Act). The statement has to be made before second reading. On 8th November 2007, Lord Darzi of Denham, the Parliamentary Under-Secretary of State for Health made the following statement:

In my view the provisions of the Human Fertilisation and Embryology Bill [HL] are compatible with the Convention rights.

COMMENCEMENT

255. Clause 68 contains the relevant commencement power. Clause 64 includes power to make transitional provisions.

HUMAN FERTILISATION AND EMBRYOLOGY BILL [HL]

EXPLANATORY NOTES

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